glenmark
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January 15, 2018

**To,**
**Dy. General Manager**
**Department of Corporate Services,**
**BSE Ltd.,**
**P. J. Towers, Dalal Street,**
**Fort, Mumbai – 400 001.**

**Ref: Scrip Code: 532296**

**To,**
**The Manager – Listing,**
**The National Stock Exchange of India Ltd.,**
**Plot No. C/1, G Block,**
**Bandra Kurla Complex,**
**Bandra (E), Mumbai – 400 051.**

**Ref: Scrip Name: GLENMARK**

Dear Sirs,

**Sub: Glenmark initiates Phase IIb dose range finding study for novel molecule GRC 27864**

With reference to the subject mentioned above, kindly find attached media release which is self-explanatory.

Request you to kindly take the same on record.

Thanking you,

Yours faithfully,
**For Glenmark Pharmaceuticals Limited**

**Harish Kuber**
**Company Secretary & Compliance Officer**

**Encl:** as above

**Glenmark Pharmaceuticals Ltd.**
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**Press Release** **For Immediate Release**

# Glenmark initiates Phase IIb dose range finding study for novel molecule GRC 27864

*GRC 27864 is a potent, selective, and orally bioavailable inhibitor of microsomal prostaglandin E synthase-1 (mPGES-1), a novel therapeutic target in pain management*

***Mumbai, India; January 15, 2018:*** Glenmark Pharmaceuticals, a global pharmaceutical company, today announced that the company has been granted permission by the Directorate General of Health Services, Central Drugs Standard Control Organization (CDSCO), Government of India, to conduct a Phase IIb dose range finding study to evaluate safety and efficacy of GRC 27864 in patients with moderate osteoarthritic pain. GRC 27864 is a potent, selective, and orally bioavailable inhibitor of microsomal prostaglandin E synthase-1 (mPGES-1), a novel therapeutic target in pain management, which is up-regulated under inflammatory conditions.

***Glenn Saldanha, Chairman and Managing Director, Glenmark Pharmaceuticals said, "We are excited that GRC 27864 is moving forward in clinical development and this validates our focus and commitment to develop potential first-in-class molecules. In spite of several available treatment options, there is significant unmet medical need in chronic pain. We believe that GRC 27864, through its novel mechanism of action, will be able to potentially improve patients' quality of life."***

The Phase II study is planned in India in 624 patients of osteoarthritis of the knee and hip to evaluate safety, efficacy and; biomarkers to characterize novel mechanism differentiated from existing NSAID's and selective COX-2 inhibitors. Primary objective of the study is to evaluate safety and tolerability of GRC 27864 given orally at daily doses of 10 mg, 25 mg and 75 mg for 12 weeks compared to placebo, in patients with moderate osteoarthritic pain.

DCGI granted permission to conduct the Phase II study based on the results of three Phase I studies conducted in healthy adult and elderly volunteers. Single oral dose up to 1000 mg and multiple oral doses up to 130 mg/day (for 28 days) of GRC 27864 were well tolerated in these studies without any dose limiting adverse events. Pharmacodynamic biomarker data generated in phase 1 studies also demonstrated adequate target inhibition.

**About Glenmark Pharmaceuticals Ltd:**

Glenmark Pharmaceuticals Ltd. (GPL) is a research-driven, global, integrated pharmaceutical organization. It is ranked among the top 75 Pharma & Biotech companies of the world in terms of revenue (SCRIP 100 Rankings published in the year 2017). Glenmark is a leading player in the discovery of new molecules both NCEs (new chemical entity) and NBEs (new biological entity). Glenmark has several molecules in various stages of clinical development and is focused in the areas of oncology, dermatology and respiratory.

The company has a significant presence in the branded generics markets across emerging economies including India. Glenmark has 16 manufacturing facilities across five countries and has six R&D centers. The Generics business of Glenmark services the requirements of the US and Western European markets. The API business sells its products in over 80 countries, including the US, various countries in the EU, South America and India.

**For further information, please contact:**

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